Remarks

The bottom of page 2 of the office action of March 10, 2010, says that the claims "...recite a diagnostic (toxicology) specimen system comprising a population of vessels (which are obviously identical) with wireless electronic tags directly attached to the vessels." However, the tags are not identical because each has a unique identifier code on it, and applicant has further amended the claims to specify that each tag has a unique identifier. This was mentioned in the application as filed at Page 12, line 19, among other places, so it is not new matter. Since each tag has a unique electronic identification code, the vessels are not identical. As a result, the members of the population at the various facilities are not identical to each other – they each will have their unique codes.

A. **Claims 1-21 and 40-44 Are Not Indefinite.**

The Examiner rejected Claims 1-21 and 40-44 incorrectly asserting that they are indefinite.

As to the rejection of claims under 35 USC Section 112, second paragraph, the Examiner is conflating the standards of Section 112, second paragraph and section 101. Section 112, second paragraph only requires that the claims have enough clarity so that those of ordinary skill in the art can understand the metes and bounds. There is no doubt that the claims are clear enough so that one of ordinary skill in the art can understand those metes and bounds.

According to the Administrative Procedure Act, a PTO Board must "hold unlawful and set aside agency actions, findings, and conclusions found to be…arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." Thus, a patent examiner must abide by the law that a patent may be obtained for "any new and useful process, machine, manufacture,

or composition of matter, or any new and useful improvement thereof, subject to the conditions of [Title 35 of the United States Code]".[1] These four categories of subject matter eligible for protection are meant to capture anything under the sun made by man.[2] A "manufacture" has been described as any man made item not found in substantially the same form in nature that is neither a machine nor a composition of matter.[3] An applicant having an invention falling into one of the categories of eligible subject matter must state the subject matter he regards as his invention with a reasonable degree of clarity and particularity.[4] In doing so, the "[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format that makes clear the boundaries of the subject matter for which protection is sought."[5] Indeed, patent examiners "should *not* reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirements."[6]

The Examiner said Applicant's claims are indefinite under 35 U.S.C. 112, second paragraph. The Examiner concedes that the vessels are a manufacture, but apparently claiming them as being in different locations and taking into account their movement between the facilities causes confusion, in the Examiner's mind. The claims cover a situation that may exist only momentarily, but it will exist. The fact that the claims cover a situation that may not be permanent as to a particular set of vessels does not make them indefinite.

---

[1] 35 U. S. C. 101.

[2] *Diamond v. Chakrabarty* 447 U.S. 303, 309, 206 USPQ 193, 197 (1980).

[3] 1 DONALD S. CHISUM, *Chisum on Patents* § 1.02[3] (2006) discussing 1 W. Robinson, *The Law of Patents for Useful Inventions* 270 (1890).

[4] MPEP 2173.02.

[5] MPEP 2173.01.

[6] MPEP 2173.02 (emphasis added).

The Examiner ultimately concludes (bottom of page 7 of the March 10, 2010 office action) that the location recitations should be given no weight in the article of manufacture claims, without citing authority for her position. Applicant believes the location definitions are to be given weight, but even if they were not given weight the result would simply be very broad claims to manufactures, still statutory and still definite. Applicant may claim a manufacture under 35 U.S.C. 101, and further specifying their temporary locations does not render such claims indefinite.

Patent claims frequently recite elements in various positions, and those positions are attributes of the elements that are given weight in the evaluation of patentability. Literally thousands of issued U.S. patents employ the term "located at" or some very similar variation thereof in their claims to describe the subject matter protected. Attached as Exhibit A are claims from 18 patents where the location of an article of manufacture or component thereof is mentioned in a claim. Two new ones are added in this June 2010 amendment. Did the Patent and Trademark Office mistakenly issue all of these patents?

The Examiner went on to observe that "the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.'' Applicant's claims 1-17, 21, 40-41 mention transporting the vessels between the claimed facilities, and the word "transporting" negates this interpretation. It would be a very unusual thing to say "I am transporting this vessel from a shelf in the laboratory to the work bench," or the like. In particular, Claim 18 uses the term "shipping," hardly an intra-lab movement. New claims 45-47 reinforce this "not all in one lab" interpretation.

The Examiner cites no authority for her finding that the recitation of a population of vessels at the locations enumerated in Applicant's claims is to be given no weight, and indeed, counsel has found none in his research. Nor is there valid precedent for the analysis that one ignores words of claims in a section 112 evaluation if, by themselves, they would not constitute patentable subject matter under section 101. The dissection of a claim to pick and choose elements that may or may not be statutory subject matter has long been eschewed. *In re Deutsch*, 553 F.2d 689, 693, 193 U.S.P.Q. 645 (CCPA 1977).

Of course, applicant does not concede that the location recitations raise a section 101 issue. As the Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. 101 so as to include "anything under the sun that is made by man" as statutory subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980). Certainly, a population of biomedical specimen collection vessels, at least some members of the population being located at vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility and additional members of the population being transported between the facilities falls within that expansive definition. What is claimed is a population, with members of the population at the recited locations, not the locations themselves.

Instead of being language to be ignored, recitations of the location of elements can be a critical element in determining patentability under section 103. For example, as is well known, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) In *Gordon*, the claimed device was a blood filter assembly for use during medical procedures wherein both the

inlet and outlet for the blood were **located** at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. This Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Court of Appeals reversed, finding that if the prior art device was turned upside down, it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged. MPEP 2143.01 Hence, whether the inlets were **located** at the top or the bottom was critically important.

In fact, claims have been held invalid for NOT reciting a location. If the specification discloses that a particular location is critical or essential to the practice of the invention, failure to recite or include that particular location in the claims may provide a basis for a rejection based on the ground that those claims are not supported by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the **location** of the step in the process. The court was convinced that the cooling bath and its **location** were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure. MPEP 2174.

Similarly, in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) claims to a sectional sofa comprising, inter alia, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened during prosecution by removing the limitation defining the **location** of the control means.

The Examiner said claim 18 is unclear and indefinite as to whether the population members at the facilities differ from one another. That is immaterial. Such lack of specificity signifies breadth, not indefiniteness.

The Examiner also said that Applicant's Claim 18 "is indefinite as to which data are stored at the vessel distribution facility."[7] Without conceding the correctness of the rejection, claim 18 has been made more specific as to the data being on the tag at the vessel distribution facility.

Claim 19 was said to have problems with "distributing" and "specimen container." The claim has been amended to recite "distributing" to "facilities," more in keeping with the examiner's connotation, and also to change "container" to "vessel" to provide consistency of terminology.

Definiteness of claim language under 35 U.S.C. 112 is analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time of the invention.[8] Potential infringers need to be apprised of the scope of patent protection defined by a patent's claims, and they would have no problem with Applicant's claims in that regard.

---

[7] Id.

[8] MPEP 2173.02.

Figure 5 of Applicant's application illustrates, schematically, a specimen container supplier, a specimen collection site, and a laboratory. One of ordinary skill would understand that Applicant claims a system that includes a population of vessels. The vessels are at specified facilities and the vessels are *transportable* or transported between the facilities. Applicant's claims are not indefinite for failing to describe statutory subject matter. Nor are Applicant's claims indefinite for claiming data, or for limiting claim elements to specified locations. Therefore, the Examiner's rejections of Claims 1-20 and 40-44 as indefinite should be reversed.

To the extent the examiner's position is based upon the vessels at the vessel distribution facility, specimen collection facility and specimen testing facility not being structurally different from each other, such analysis is inapt when it comes to claims 19 – 21 and 44 and new claims 48 and 49. Claim 48 specifically adds structural distinctions in the members of the population located at the vessel distribution facility contain no specimen and members of the population located at the specimen collection facility and specimen testing laboratory facility contain specimens.

In claims 19-21, 44 and 49 the vessels are differentiated by the data that is stored on their respective electronic memory tags.

In the March 10, 2010, office action page 17, the examiner quotes page 11 of applicant's specification that discusses label 4 for the vessel, and she concludes that the label is the same as Petrick's business form. Her conclusion is erroneous. Applicant does not suggest, and certainly does not claim destruction of the label to de-associate the device from the form, as is required by Petrick's claim. Again, the examiner is not limiting the comparison of what applicant claims to what Petrick claims.

B. Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41, and 44 Are Not Anticipated by Petrick.

The Patent Office accorded Applicant a filing date of December 14, 2000 for this application. After several official exchanges between the Examiner and Applicant, an Office Action mailed January 15, 2004, rejected claims of the application for the first time under 35 U.S.C. 102(e) over U.S. Patent 6,535,129 to Petrick, which issued March 18, 2003 on an application filed November 17, 2000. Applicant submitted Rule 1.131 declarations of co-inventors Jason Bowman, Danny Charles Bowman and David Michael Lewis showing invention of the claimed subject matter antedating the filing date of Petrick to remove the reference as prior art.[9]

The examiner found no fault in the proof that applicant antedates Petrick. Instead, she "indicate[d] that [Applicant's and Petrick's] inventions are the same"[10] because, she asserted, Applicant's specification and Petrick's patent disclose common elements.[11] The Examiner found that, since both Applicant and Petrick disclose specimen vessels and business forms,[12] Applicant's application is claiming the same patentable invention as Petrick's patent.[13]

---

[10] Paragraph 18 of Office Action mailed January 10, 2006, Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

[11] Id.

[12] Id. The Examiner apparently asserted that Petrick's business form and Applicant's wireless electronic memory tag are one and the same with her statement that "…Applicants claim a population of vessels with attached business forms (the wireless electronic memory tag)." This is so even though the Examiner's version of "the same patentable invention" analysis reads features disclosed in Petrick's specification into its claims. Thus, under her analysis, Petrick's business form should resemble one of the paper versions disclosed in Petrick's specification at Figs. 3a and 3b, rather than the wireless electronic memory tag claimed by Applicant. So, her "same patentable invention" analysis improperly reads limitations into the claims and she appears to have inconsistently applied her own improper analysis.

[13] Paragraph 18 of Office Action mailed January 10, 2006, Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

37 CFR 41.203(a) (revised from 37 CFR 1.601(a)) states the general rule for determining whether an application is claiming the same patentable invention as a patent thusly:

> *Interfering subject matter.* An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing part and vice versa.

The predecessor of the Court of Appeals for the Federal Circuit held in *In re Eickmeyer*[14] that the PTO cannot deny an applicant an interference on the grounds that the applicant and a patentee are not interfering in fact and also deny the applicant the opportunity to swear behind the patent on the grounds that the applicant is claiming the same invention as the patentee. Accordingly, since an interference-in-fact requires a two-way analysis of the "same patentable invention" set forth in rule 41.203(a), such must also apply to the interprctation of Rule 1.131.

The Trial Section of the Interferences Division of the Board of Patent Appeals and Interferences in *Winter v. Fujita*[15] set forth a two-way analysis to determine the existence of an interference-in-fact. The Court of Appeals for the Federal Circuit uses the same test. *Medichem S.A. v. Rolabo S.L.,* 77 USPQ 2d 1865 (Fed. Cir. 2006). In the first step of the analysis, the claimed invention of Petrick is presumed to be prior art to the applicant. If Applicant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the second step is undertaken in which Applicant's claim is presumed to be prior art to Petrick's, and the obviousness analysis is performed. If Petrick's claim is new and non-obvious in view of Applicant's claim, the claims describe separate patentable inventions. The claims describe the same patentable inventions only if Petrick's claimed invention

[14] 602 F.2d 674, 202 U.S.P.Q. 655 (CCPA 1979).

[15] 53 USPQ2d 1234, 1243 (1999), reh'g denied, 53 USPQ2d 1478 (BPAI 2000).

anticipates or renders obvious Applicant's claimed invention *and* vice versa.[16] The analysis refers only to the parties' claims, not the remainder of the specifications.

The MPEP agrees:

> As provided in **37 CFR 41.203(a)**, an interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa. An applicant who is claiming an invention which is identical to, or obvious in view of, the invention as claimed in a domestic patent or patent application publication cannot employ an affidavit under **37 CFR 1.131** as a means for avoiding an interference with the reference. To allow an applicant to do so would result in the issuance of two patents to the same invention.
>
> Since **37 CFR 1.131** defines "same patentable invention" in the same way as the interference rules (**37 CFR 41.203(a)**), the USPTO cannot prevent an applicant from overcoming a reference by a **37 CFR 1.131** affidavit or declaration on the grounds that the reference claims applicant's invention and, at the same time, deny applicant an interference on the grounds that the claims of the application and those of the reference are not for substantially the same invention. See *In re Eickmeyer*, 602 F.2d 974, 202 USPQ 655 (CCPA 1979). Where, in denying an applicant's motion in interference to substitute a broader count, it is held that the limitation to be deleted was material for the opponent patentee, this constitutes a holding that the proposed count is for an invention which is not the "same patentable invention" claimed by the reference. Therefore, the applicant may file an affidavit or declaration under **37 CFR 1.131** to overcome a prior art rejection based on the reference. *Adler v. Kluver*, 159 USPQ 511 (Bd. Pat. Int. 1968). (MPEP Section 715.05)

B.1. Evaluation of Applicant's System Claims 1-17 and 40-43

Petrick's Claims 1 and 7 read:

> 1. A business form comprising:
>
> a first portion providing chain of custody information therein; and
>
> a second portion linking said form with at least one specimen;
>
> wherein said business form further includes a wireless identification device associated therewith that electronically provides at least an identifier in response to a query for automatically establishing the chain of custody of said specimen,

[16] Id.

said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form. (emphasis added; the emphasized language is in all of Petrick's independent claims)

7. The business form of Claim 1 wherein said wireless identification device is adhered directly to the specimen or to a container containing the specimen.

And Applicant's Claim 1 states:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other membcrs of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members being transported between the facilities,

wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information directly attached thereto such that the tag remains attached to the vesscl at the facilities and as the vessel is transported between facilities.

Thus, Petrick requires the *wireless identification device to be associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form*, necessarily implying some physical connection of the form to the wireless identification device. Applicants claims, on the other hand, all have a requirement that a specimen collection vessel have a wireless electronic memory tag directly attached to the vessel at the vessel distribution facility, not mentioning a business form at all, much less first and second portions of a form.

In thc March 10, 2010, office action page 17, the examiner quotes page 11 of applicant's specification that discusses a label 4 for the vessel, and she concludes that the label is the same as Petrick's business form. Her conclusion is erroneous. Applicant does not suggest, and certainly does not claim destruction of the label to de-associate the device from the form, as

required by Petrick's claim. Again, the examiner is not limiting the comparison of what applicant claims to what Petrick claims.

B.1.(a) Assuming Petrick is Prior Art to Applicant for 41.203(a)Test

Assuming Petrick's claim is prior art, Applicant's claim is novel. Applicant's claim describes a diagnostic specimen system including a population of collection vessels having members at specified locations. Petrick's claim does not disclose multiple vessels at the specified locations. Applicant's claim is therefore new in view of Petrick's claimed invention.

Applicant's diagnostic specimen system is also not an obvious variation of Petrick's business form. Nothing in Petrick's claim teaches or suggests the vessels at various locations set forth in Applicant's claim. Thus, Applicant's claim is not an obvious variation. Applicant's claim is not even directed to similar subject matter. Petrick claims a business form; Applicant claims a system comprising a population of vessels. Petrick's wireless identification device (WID) is attached to the form in claim 1-- not the specimen collection vessel. Petrick's Figure 3B embodiment discussed at column 5, lines 19-36 (and her claim 7) suggests removing the wireless identification device from the form as part of a label used to seal the vessel. But, that still completely omits (and contraindicates!) vessels with the tags at the vessel distribution facility, since Petrick's seal can not be added until the specimen has been collected. Petrick emphasizes the importance of keeping the tag with the form, (at least until conspicuous removal takes place), so it would not have been obvious to put the tag on at the vessel distribution facility. Therefore, Applicant is not claiming the same patentable invention as Petrick's Claim 1 or 7 since doing so would negate what Petrick takes pains to make happen.

B.1.(b) Assuming Applicant Is Prior Art to Petrick for 41.203(a) Test

If Applicant's claim is assumed to be prior art to Petrick's, the same result obtains. Petrick's claim requires a new business form having two portions and a particular association between the business form and the wircless identification device. Applicant's claim does not disclose or suggest a business form (much less one having two portions) or any particular relationship between such a form and an identification device. The Examiner apparently contends that Applicant's bar code 7 (see office action of April 11, 2009, page 17) is a business form. Such a label is far from a business form as claimed by Petrick, which requires that the "*wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.*" Thus, Petrick's claim is non-obvious in view of Applicant's claim.

B.2. Evaluation of Applicant's Method Claims 18-21 and 44

Petrick's Claim 8 recites:

> A method of establishing a chain of custody comprising:
> associating a business form and a radio frequency identification device with at least one object, *said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form*; and
> using both the business form and the radio frequency identification device in combination to establish a chain of custody for the object including querying said device and receiving a response that is automatically used to establish said chain of custody.

And Applicant's Claim 18 reads:

> 18.A method for electronically storing data on a diagnostic or toxicology specimen vessel and remotely reading data from the vessel comprising:

at a vessel distribution facility providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, with data electronically stored on the electronic memory tag;

shipping members of the population having the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to a specimen collection facility; and

subsequently reading the stored data from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

B.2.(a) Assuming Petrick Is Prior Art to Applicant for 41.203(a)Test

The Examiner asserts that Applicant's Claim 18 and Petrick's Claim 8 claim the same patentable invention, but Petrick's claim does not teach or suggest Applicant's "at a vesscl distribution facility providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, with data electronically stored on the electronic memory tag." Nor does Petrick teach or suggest that memory tags should have stored data at a vessel distribution facility. Petrick's discussion of its Fig. 3B teaches away from putting data or the specimen vessel at a vessel distribution facility, since adhering the seal to enclose a specimen in Petrick is intended to apply the RFID tag at the same time. This step is how Petrick ensures the chain of custody, so it cannot be omitted.

Nor does Petrick's claim teach or suggest Applicant's Claim 19 with similar recitations, nor does Petrick claim collecting and storing an electronic signature, as in Applicant's Claim 20 and 44. So, Applicant's Claims 18-21 and 44 are new and non-obvious in view of Petrick's Claim 8.

B.2.(b) Assuming Applicant Is Prior Art to Petrick for 41.203(a)Test

Neither of Applicant's Claims 18-21 or 44 teach or suggest the business form or Petrick's claimed particular association between Petrick's business form and its wireless identification

device *"associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form."* Applicants claims do not disclose or give a reason to use a buiness form and wireless identification device in combination to establish a chain of custody for the object. So, Petrick's Claim 8 is new and non-obvious, and Applicant is not claiming the same patentable invention as the patent.

The Examiner insists that Applicant and Petrick claim the same patentable invention without showing that Petrick's claims anticipate or render Applicant's claims obvious. No doubt the Examiner has not done so because the task is impossible: Applicant is not claiming the same patentable invention as Petrick. Applicant can properly swear behind Petrick, so the rejections of Applicant's claims using Petrick as prior art should be withdrawn.

As regards the art rejection over Petrick (US 6,535,129), the Examiner entirely relies on not being required to give the recitations of the locations of the vessels weight in order to sustain her position. Thus, it is clear that if those recitations are to be given meaning, the art rejections that rely on Petrick must be withdrawn. Recall that the Petrick reference is in the case because the Examiner refuses to accept Applicant's Declarations swearing behind Petrick, saying that Applicant and Petrick are claiming the same invention. She reaches that conclusion by disregarding the location limitations of Applicant's claims. There is no public policy served by the Examiner's novel theory. The claims are understandable, so the metes and bounds are understood, and the subject matter of the claims is clearly within *Chakrabarty's* scope.

B.3. Applicant's Application and Petrick Are Classified in Unrelated Classes.

The PTO often asserts that inventions are patentably distinct and supportive of two patents in making restriction requirements. According to MPEP Section 808.02 separate classifications is a reason for insisting on restriction of distinct inventions. Petrick is classified in U.S. Class 340/572.1, relating to electrical communications, completely unrelated to electrical communications is U.S. Class 436/56, where applicant's published application has been classified. The PTO first classified Applicant's application in a separate class from that in which Petrick's patent is classified, establishing that the inventions are independent and distinct. MPEP § 2301.03 points out that claims that are patentably distinct, they are not interfering. The examiner now erroneously finds that the application and the patent are claiming the same patentable invention.

B.4. Responding to the Examiner's Comments

Applicant's claim 1 recites a population of biomedical specimen collection vessels, at least some members of the population being located at a vessel distribution facility, other members of the population being located at a specimen collection facility, further members of the population being located at a specimen testing laboratory facility, and additional members being transported between the facilities. Petrick's claims 1 and/or 7 do not have members of populations of vessels at these various facilities, particularly members at the vessel distribution facility and having the wireless tag directly attached. The Examiner asserts that the location of the claimed vessels does not bear patentable weight. As pointed out above, the examiner is wrong in that respect, and that may contribute to her error concerning whether or not applicant and Petrick are claiming the same patentable invention.

In discussing claim 18, the Examiner asserts that Petrick's claim 8 essentially repeats Applicants' method of electronically storing information. Once again, the examiner is ignoring

material limitations of Petrick's claim, including the limitations "said wireless identification device being associated with a form of such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form." Applicants' claim has no such limitation.

On page 17 of the Answer, the Examiner apparently tries to comply with the two-way test for determining whether Applicant and Petrick are claiming the same patentable invention, but she is unsuccessful. The Examiner quotes a passage from Applicant's specification, page 11. The passage that the Examiner refers to says electronic memory tag 3 can include a carrier label 4 which has a front face 5 and a rear face 6, with an identification bar code 7 on the front face. A text area can also be provided for printing, typing or writing pertinent information on the front face carrier label 4.

The Examiner's position is that this defines Applicant's claim to the point of causing the claim to read on that embodiment and that the subject matter disclosed in connection with Figure 2 is the same as what Petrick claims with respect to its business form. However, Petrick's business form as claimed in ALL of Petrick's claims includes two portions and a wireless identification device that is associated with a form, such that the associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through a visual inspection of the form. Nothing in the passage of Applicant's specification cited by the Examiner teaches or suggests de-associating the device from the form resulting in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form. The readily discernable partial destruction is a concept that is core to Petrick's claims, but totally absent from Applicant's claims. Thus, applicant's claims cannot make Petrick's claim obvious,

so different patentable inventions are being claimed, and the 1.131 declaration is to be given effect.

In the first full paragraph on page 17, she reaches the conclusion "Petrick's invention would be either anticipatory for, or an obvious modification of Applicant's invention." She points out that Petrick's claim 8 recites establishing a chain of custody. From there she bootstraps that a chain of custody for a biological specimen inherently comprises distributing, transferring, and analyzing the specimen in the containers. Petrick's claim 8 does not mention any of that --- not even "biology." The phrase "chain of custody" does not necessarily imply the examiner's phrase which is "distributing, reading, transferring and analyzing the specimen in the container," nor the specificity of Applicant's claims. Furthermore, Petrick's claim 8 does not refer to a wireless tag being attached to the container.

Applicant's claim 19 recites providing a population of biomedical specimen vessels each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility, distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility, and collecting a specimen from a donor in the specimen container at the specimen collection facility. Petrick's claim 8 requires use of both the RFID tag and the form in combination to establish a chain of custody, so Petrick's form is critical. Applicant claims no form.

Applicant's claim 21 goes on to recite the step of transporting the member vessel with the collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical test performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory. The Examiner finds all that in Petrick's simple phrase "chain of custody?" Recall again the claim is to be compared to the claim, not claim vs.

specification. The Examiner's conclusion that claim 8 of Petrick's patent and Applicant's claim 18 and dependents thereon are claiming the same patentable invention is wrong.

Nor would it have been obvious to modify Petrick's claimed invention to arrive at Applicant's claimed invention. Petrick's specification (not its claim) does discuss showing a chain of custody from the collection custodian 54, through an intermediate custodian 56 to the laboratory 52 (Fig. 1). There is no discussion of how the specimen container gets to the collection custodian, so not even Petrick's specification has a vessel distribution facility, much less Petrick's claims.

At column 3, lines 38-55, Petrick emphasizes the importance of the RFID chip 106 being within the chain of custody form 102, to help assure integrity of the chain of custody. The RFID chip is attached to the specimen collection vessel by the collection custodian, so it cannot be attached at the vessel distribution facility, as is the case with Applicant's claimed invention.

Petrick emphasizes the association of the RFID chip with the form by the fact that the chip's disassociation from the form is to be evident. This relationship of the chip to the form is fundamental to Petrick's chain of custody scheme and is a material limitation in his claims. But this fundamental relationship teaches away from applicant's invention, in which the tag is applied to the vessel before it gets to the "collection custodian" (and no form is mentioned). Thus, applicant's claimed invention could not have been obvious from Petrick's claimed invention. The parties are claiming different inventions.

The examiner pointed out on page 18 of the May 11, 2009 office action that applicant's claims did not recite that the wireless tag is *directly* attached to the vessel, justifying her saying they may read on something like what Petrick claims. The claims have been amended to recite

such direct attachment. This is not new matter, since it direct attachment is seen in Figure 1 of applicant's original application.

C. Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 44 Are Not Anticipated by Berney.

C.1. Claims 1, 6-7, 9, 14-15, 21, and 40-41 Are Not Anticipated by Berney.

Applicant's claimed invention relates to improvements in identification, logistics control, and information management for biomedical specimens collected for diagnostic or toxicology testing. Diagnostic and toxicology specimens are typically collected for analytical testing from donors at collection sites such as hospitals, clinics, or doctors' offices. These specimens are collected in primary specimen containers specifically designed to completely and safely contain the specimens during handling and shipment in order to preserve the integrity of the specimens and to protect the health of persons who come in contact with the containers. In addition, toxicological specimen containers are typically provided with tamperproof locks or seals to ensure that the integrities of the toxicological specimens are not breached by unauthorized persons or by mishandling of the containers.

Successful testing requires the collection, recording, and maintenance of essential information about each diagnostic or toxicology specimen. Such information includes the identity and nature of each specimen, the identity of the specimen donor, the test or tests to be performed on the specimen, the identity of the person collecting the sample, the time and place of collection, and the results of tests performed on the specimen. Also, toxicology specimens typically require written authorizations signed by their donors. Because most specimen collection sites do not have testing laboratories on site, the specimens are typically sent to remote reference laboratories. Accordingly, the pertinent information about a particular specimen must

be accurately communicated to the laboratory which tests the specimen, and the laboratory must in turn accurately report the test results for that specimen back to the site where the specimen was originally collected or to another remote site.

Prior to applicant's invention, the recording, maintenance, and communication of specimen and testing information was usually done using preprinted, duplicate-page forms having spaces for manually entering designated information onto the forms. Duplicate copies of the completed forms were used to communicate and record information among and between multiple departments or sites involved with the handling or testing of a specimen. The primary specimen containers and copies of the associated forms were typically maintained together by placing them together in secondary containers such as boxes or sleeves. These secondary containers are then transported to a reference laboratory to conduct the required tests on the specimens.

Reliable, legal evidence linking the specimen to be tested to the donor is critical, particularly for toxicology specimens such as urine specimens to be tested for illicit drugs.

Because the specimens going to a particular laboratory originate from multiple remote collection sites, the collection and delivery of such specimens requires coordination between the collection sites, the laboratory, and a courier. Because many collection sites have only a sporadic need for diagnostic or toxicology testing, it is often inefficient for a designated courier to visit a potential collection site daily or semi-daily to possibly collect specimens for delivery. Avoiding such inefficiency requires a collection site to notify either the laboratory or a courier each time specimens are awaiting collection for delivery to the laboratory, causing a different type of inefficiency.

Reference laboratories typically included automated handling and testing equipment. Such laboratories had automated sorters and conveyors for routing specimens to testing stations and testing equipment that automatically performed the required tests on the specimens with minimal manual human intervention. Even such automated laboratories have needed to receive and inventory specimens from remote specimen collection sites by manually unpacking each specimen and the associated forms from their boxes or sleeves. Once testing had been performed on a specimen, a laboratory typically recorded the test results manually on the associated forms and then reported the test results by sending the completed forms to the originating specimen collection site or other selected destination.

Those methods for information management and logistical control for biological specimens collected for diagnostic or toxicology testing cause a number of difficultics. The use of written forms and written labels to record, maintain, and communicate specimen information is especially problematic. Manual entry of information onto forms or labels at collection sites and laboratories is labor intensive and causes delays in processing the specimens and information. Also, written forms or labels are sometimes illegible or became obliterated by handling or spills, causing a loss or miscommunication of essential information. Furthermore, it is necessary to physically maintain copies of the forms with the associated specimens. These forms added bulk to transport packaging for the specimen containers, and there is a risk of loss or dissociation from the specimens. In addition, the forms have to be individually handled and scanned or read when received by a reference laboratory, adding labor cost and causing delays that lead to underutilization of the automated laboratory handling and test equipment. Lost or dissociated forms could cause potentially harmful delays in the testing or reporting of diagnostic test results for distressed donors experiencing medical emergencies. In addition, if a form

containing an authorization signature of a toxicology specimen donor was lost or misplaced, the test can not be performed until the donor again authorizes the test.

Berney discloses a system for registering useful information during analyses of blood in conventional glass test tubes 1.[17] Berney's electronic memory labels 4 are attached to supports 31 that are fixed on the test tubes 1[18] in a testing laboratory at the time of sample analysis.[19] The supports 31 have spring like shape for attaching the test tubes[20] and rest on a base 33 including a bus system 46 for transferring information to and from the labels 4 during analysis.[21]

Berney's abstract says the label is attached to the test tube with a detachable support, not the sort of affixation used to accompany a specimen collection vessel transported from a distribution facility to a collection site and then to a lab, particularly if a secure chain of custody is important. Figure 1 of Berney illustrates that the tag is held to the test tube in fingers, reinforcing the notion of detachability. Column 2, lines 28-30 of Berney say these are spring-like fingers "allowing a firm fixation of said labels onto the test tube during the time analysis." (emphasis added) At other times (like before the specimen is in the test tube, or at a specimen collection facility) affixation is apparently not important; since it is not mentioned by Berney. There is no teaching or suggestion supporting the examiner's position that Berney suggests Applicant's invention.

---

[17] Col. 1, Line 11 of Berney.

[18] Col. 2, Lines 22-24 of Berney.

[19] Col. 1, Line 18; Col 1, Line 36; Col. 1, Lines 64-65; Col. 2, Line 29; Col. 3, Lines 18-25; Col. 4, Line 7 of Berney (Emphasis added).

[20] Col. 2, Lines 28-30 of Berney.

[21] Col 2, Lines 34-56, Figs. 3 and 4 of Berney.

Berney does not disclose and is not concerned with vessels at a vessel distribution facility or a specimen collection facility. One of ordinary skill in the art would see Berney's spring-like supports 31 as only a temporary affixation to a test tube within the laboratory. At column 2, lines 29-30, Berney's statement that these allow a fixation of the label 30 onto the test tube 32 at the time of analysis clearly suggest that affixation at that time is the only time of concern to Berney. In particular, a spring-loaded mount, which is obviously removable, does not suffice for a chain of custody proof system.

Berney anticipates Applicant's claims only if each and every element as set forth in the claims is found either expressly or inherently described.[22] While she acknowledged that Berney does not expressly disclose Applicant's claimed inventions, the Examiner asserted that Berney inherently discloses Applicant's claimed population of biomedical specimen collection vessels.[23] But, to be inherent, the features of Applicant's claimed invention must *necessarily* be present in the Berney disclosure,[24] and Applicant's specified vessel locations are not even consistent with Berney's disclosure, much less *necessarily present*. Berney's label provides a temporary mount to a test tube during analysis of the test tube contents in a laboratory; only one of the three facilities described by Applicant's claims. Thus, Berney does not inherently disclose any of Applicant's Claims 1, 6-7, 9, 14-15, 21 and 40-41. The Examiner's rejections of these claims should be withdrawn.

C.2. Claim 19 Is Not Anticipated by Berney.

Berney describes its process of performing blood analysis thusly:

---

[22] MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[23] Paragraph 6 of Office Action dated January 10, 2006.

[24] MPEP 2112 (IV.).

> [F]irstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central data base into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient.[25]

Thus, Berney's labels are attached in the lab and one of ordinary skill would appreciate that the labels are also removed in the lab, so that the labels can be reused with another test tube after the information is transferred from them to a centralized data bank. There is no reason to attach electronic labels to Berney's test tubes prior to sample collection because Berney says reference data of the patient is not transferred to the labels until during the time of sample analysis.[26] Thus, Berney is concerned with recording specimen analysis data, not complete chain of custody information, so Berney does not disclose electronic memory tags attached to vessels at a distribution facility, or distributing vessels having electronic memory tags to a collection facility. Therefore, Berney does not anticipate Applicant's Claim 19, and the Examiner's rejection of the claim should be withdrawn.

C.3. Claim 44 Is Not Anticipated by Berney.

Berney does not disclose collecting and storing the electronic signature of a specimen donor on an electronic memory tag at a specimen collection facility. Berney does not even disclose collecting an electronic signature, much less collecting and storing one at a collection facility. The specimen donor, whose signature collection features in Claim 44, is not even

---

[25] Col. 3, Lines 18-25.

[26] The Examiner argues at Paragraph 18 of the Office Action mailed January 10, 2006, Regarding anticipatory rejections over Berney under 102(b) that "[t]here is no way [Berney's] tag can be attached to the test tube *after* the collected sample was transported to the lab," but this assertion ignores the fact that Berney's test tube can be associated with a patient at the time of sample collection by means other than identifying the patient on electronic labels. The fact that Berney does not disclose such means evidences the purpose of Berney's labels: to store analysis data during the time of specimen analysis rather than to record chain of custody data.

present when Berney is using his clip-on test tube electronic label. So Berney does not anticipate Applicant's Claim 44, and it would not be obvious to perform the method of claim 44 from Berney, so the Examiner's rejection of the claim should be withdrawn.

D. Claim 21 Is Patentable over Berney.

The Examiner rejected Claim 21 as anticipated by Berney, she also acknowledged that Berney does not disclose transporting vessels to a specimen-testing laboratory. But, she reasons, since transporting vessels is conventional medical practice, one of ordinary skill would have transported Berney's vessels, "because it allows tracking the vessels using Berney's inventive electronic tags on the specimen vessels." No, it does not. Berney does not put his clip-on identifier on the test tube until the specimen is in the lab, so it could not be useful to track the specimen at the specimen collection facility.

E. Claims 5, 8, 13 And 18 Are Patentable Over Petrick or Berney in View of Leuenberger.

E.1. Claims 5 and 13 Are Patentable.

The Examiner concludes that it would have been obvious to store data including the identity of a specimen vessel and product information about the vessel on a memory tag. She said one of ordinary skill would modify Petrick to include such information 'because vessels (containers) from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is

always conventionally provided with all manufactured products, especially test tubes (vessels, containers).'[27]

Of course, Petrick is not prior art, but still, the reference fails to teach or suggest storing product information on an electronic memory tag attached to a specimen collection vessel. Leuenberger says that paper labels have been used to store product information on blood packs, but that the paper labels exhibit certain disadvantages overcome by the use of microporous plastic film labels.[28] Thus, Leuenberger suggests paper or plastic film labels, but fails to suggest using an electronic memory tag to store product information. Berney discloses storing information on an electronic label in a laboratory during the time of specimen analysis. Neither Petrick, Berney or Leuenberger suggests storing product or manufacturer information on an electronic memory tag at a vessel distribution facility. Even if the Examiner were correct in asserting that product information "is always conventionally provided with all manufactured products,"[29] that fact says nothing about storing that information *on an electronic memory tag*, as Applicant claims. To say that one of ordinary skill would have combined Petrick or Berney with Leuenberger to produce an electronic memory tag having stored thereon manufacturer or product information is merely bridging the gap between the references by using that which Applicant teaches against its teacher.

Moreover, Petrick and Berney do not indicate that the maker of the vessel is of any concern. Petrick is all about business forms; indeed Petricks' wireless identification device starts out associated with the form such that de-associating the device from the form results in at least

[27] Paragraph 11 of Office Action mailed January 10, 2006.

[28] Col. 1, Lines 18-55 of Leuenberger.

[29] Paragraph 11 of Office Action mailed January 10, 2006.

partial destruction of the form in a manner that is readily seen through visual inspection of the form. How and why one would research the collection vessel maker when using the Petrick business form is not at all clear from Petrick. Berney's applying his wireless device to the apparently reusable test tube certainly suggests that the original maker of the test tube is unimportant.

The May 11, 2009 office action says that Petrick's and Berney's test tubes are specifically designed for handling information on the manufacturer or supplier, but counsel can find nothing in either reference saying such a thing. Unless the examiner can provide a pinpoint citation to this alleged teaching, the rejections of Claims 5 and 13 should be withdrawn.

E.2. Claim 8 Is Patentable.

Claim 8 describes a diagnostic specimen system including a population of collection vessels each having attached thereto both an electronic memory tag and a label having an identifying bar code. Petrick is not prior art to Applicant's application, and Berney discloses an electronic label for registering all useful information during the time of analyses of a specimen contained in a test tube; Berney does not teach or suggest a label having an identifying bar code attached to its test tubes. And, although Leuenberger discloses the use of microporous plastic film labels that may include an identifying bar code 16,[30] one of ordinary skill would find no reason to add Leuenberger's bar code to the test tubes disclosed by Berney because Berney's electronic label suffices for registering such information. There is no reason to add a bar code to Berney. Therefore, Applicant's claim is patentable in view of the references and the Examiner's rejection of Claim 18 should be withdrawn.

[30] Col. 2, Lines 5-55 of Leuenberger.

E.3. Claim 18 Is Patentable.

Petrick is not prior art to Applicant's application, and Berney does not disclose providing a population of biomedical specimen vessels or storing data on an electronic memory tag at a vessel distribution facility. Nor do the references disclose shipping members of a population of vessels that include electronic memory tags from a vessel distribution facility to a specimen collection facility. However one may move Berney's test tube around in his lab would not be "shipping" as claimed in claim 18. Thus, the references do not teach or suggest all of Applicant's claim limitations, so the Examiner's rejection of Claim 18 should be withdrawn.

F. Claims 16, 17, 20, 42, and 43 are patentable over Petrick or Berney in View of Hoffman or Fukuzaki.

F.1. Claims 16, 42 and 43 Are Patentable

The Examiner asserted that one of ordinary skill would have combined the electronic signature disclosed in Hoffman or Fukuzaki with Petrick's or Berney's disclosure "specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of 'the person under concern' is conventional in all diagnostic procedures."[31] Petrick, however, is not prior art to Applicant's application, and Berney does not disclose members of a population of specimen vessels at Applicant's claimed locations. Berney acknowledges no specimen collection from a donor, at all. Nor is there any apparent way to store an electronic signature of the donor of a toxicology specimen on Berney's test tubes, since

[31] Paragraph 12 of Office Action mailed January 10,2006.

the tags are attached during the time of sample analysis. The office action cites column 1, line 68 of Berney as being relevant, but it has no mention of a signature.

Neither Hoffman nor Fukuzaki suggests including an encoded electronic signature of the donor of a toxicology specimen on an electronic memory tag. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a specimen vessel having a memory tag containing an encoded electronic signature.

F.2. Claim 17 is Patentable

The Examiner asserts that it would have been obvious to combine Hoffman or Fukuzaki with Petrick or Berney to produce Applicant's Claim 17.[32] Prior art references combined to establish obviousness, however, must yield all claim limitations.[33] Applicant claims a toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel. Petrick is not prior art to Applicant's application but, even so, neither Petrick nor Berney teaches or suggests all the elements of Claim 17. Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither Hoffman nor Fukuzaki teaches or suggests a toxicology specimen system including a population of specimen vessels having wireless electronic memory tags storing data including an identification code for the vessel, the identity of the supplier of the vessel and product

[32] Paragraph 12 of Office Action mailed January 10, 2006.

[33] MPEP 2143.

information about the vessel. Therefore, Applicant's claim would not have been obvious to one of ordinary skill and the Examiner's rejection of the claim should be withdrawn.

F.3. Claim 20 is Patentable

Petrick is not prior art to Applicant's application, and neither Berney, Hoffman, nor Fukuzaki discloses a method that includes providing a population of vessels at a vessel distribution facility, distributing members to a collection facility, or collecting a specimen at the collection facility. Therefore, Applicant's Claim 20 would not have been obvious to one of ordinary skill in the art and the Examiner's rejection of the claim should be withdrawn.

G. Claims 2 and 10 are Patentable over Berney in view of RD 421048 A.

To establish a *prima facie* case of obviousness, a combination of prior art referencces must provide a reason for one of ordinary skill in the art to reach the allegedly obvious claimed invention.[34] Berney does not teach or suggest a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. RD 421048 A discloses a method for chemical management for tracking compounds within a chemical synthesis system including identification tags having passive transponders.[35] Modifying Berney to include RD 421048 A's passive transponders does not produce the diagnostic specimen system of Applicant's Claims 2 and 10 because RD421048 A does not disclose applicant's claimed vessel locations. Thus, the claims would not have been obvious and the Examiner's rejections Berney in view of RD 421048A should be withdrawn.

[34] Id.

[35] ABSTRACT of RD 421048 A.

H. Claims 3-4 and 11-12 are Patentable over Berney in View of Stevens.

The Examiner asserts that it would have been obvious "to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to 'create a link between the container, the patient and the test request forms', or any other forms associated with using this container."[36]

Stevens discloses a sample collection tube 20 and a label 40 comprising a permanent portion 50 having a barcode 90 and a peel away portion 70 for affixation to a test request form or to another container or item.[37] Berney discloses an electronic label that provides for registration of *all* useful information required for analysis of a blood sample, however, and thus *eliminates* the need for jotting down and manual transfer of information.[38]

Therefore, Combining Stevens' barcode associated with a manual entry form with Berney's disclosure would destroy Berney's purpose of eliminating manual entry of information, so one of ordinary skill would not modify the references as proposed by the Examiner,[39] and even if one were to make such a modification, the result would still not produce Applicant's claimed vessel locations. Accordingly, the obviousness rejection of each of Claims 3-4 and 11-12 is improper and should be withdrawn.

---

[36] Paragraph 14 of Office Action mailed January 10, 2006 quoting Bowman at Column 1, Line 13-18.

[37] Col. 5, Lines 25-27; Col. 6, Lines 19-21; Figure 8 of Stevens.

[38] Col. 1, Lines 30-32 of Berney.

[39] MPEP 2143.01(V.).

I. Claim 38 is Patentable over Berney in View of Bowman.

The Examiner asserted it would have been obvious to modify Berney's specimen collection vessel by adding the tamper-indicating seal disclosed by Bowman "so that any attempted tampering with the specimen will be indicated by at least partial destruction of the seal."[40] Berney discloses electronic memory labels for registering all useful information during blood analyses, and Bowman discloses a chain-of-custody bag 10 for the sealing a specimen within the bag during transportation to an analysis site.[41] The references show no reason to modify Berney in this way. Berney is not concerned with transporting vessels from a collection facility to a laboratory; everything about Berney happens in the laboratory. There is no risk of tampering that needs evidencing. Berney's test tubes are provided with caps 2 that can be removed to permit access to a blood specimen;[42] so adding Bowman's seal to Berney's test tubes would interfere with removal of Berney's cap during specimen analysis. Therefore, the references would not have suggested such a modification,[43] and the Examiner's rejection of Claim 38 should be withdrawn. If the Examiner's interpretation that the vessel distribution facility, specimen collection facility, and specimen testing laboratory facility are all within Berney's laboratory, there is no reason to add a tamper-evident seal.

J. Claim 8 is Patentable over Berney in view of RD421048 A, Stevens and Leuenberger.

---

[40] Paragraph 15 of Office Action mailed January 10, 2006.

[41] Col. 3, Lines 9-19 of Bowman.

[42] Col. 1, Line 62, Fig. 1 of Berney.

[43] MPEP 2143.01(V.).

The Examiner further asserts that it would have been obvious to include product information on a thrice-modified version of Berney "because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container."[44] Neither of these proffered motives, however, explains why one would have a reason to store supplier information *on an electronic memory tag*, as Applicant claims, rather than marking the product itself, as Leuenberger suggests. Thus, they fail to address the question whether one of ordinary skill would have had a reason to combine the references to produce the *claimed invention*. Arguments made above are also applicable here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness with respect to Claim 8, and the rejection of this claim should be withdrawn.

K. Claim 17 is Patentable over Berney in View of RD 421048 A, Stevens, Leuenberger and Hoffman or Fukuzaki.

The Examiner asserts that one of ordinary skill would have combined the encoded electronic signature of Hoffman or Fukuzaki with a thrice-modified version of Berney to produce Applicant's claimed invention.[45] Berney, however, discloses logging information concerning the person under concern in a specimen analysis laboratory, and neither Hoffman nor Fukuzaki suggest storing a signature on an electronic memory tag. Nor is there any apparent way to store an electronic signature of the donor of a toxicology specimen on Berney's labels, since they are attached during the time of sample analyses. Also, Hoffman is concerned with a method of correlative comparison of a biometrics sample for authenticating identification and Fukuzaki discloses an electronic document security system. Neither reference teaches or suggests a

[44] Paragraph 16 of Office Action mailed January 10, 2006.

specimen vessel having a memory tag containing an encoded electronic signature. Therefore, the Examiner's rejection of Claim 17 should be withdrawn.

Conclusion:

The Examiner's rejection of Claims 1-21, 38, 40-44 should be withdrawn.

In conclusion, the rejections err in numerous ways, as outlined above. Fundamentally, the Examiner disregards the material recitations of the locations of the various members of populations of vessels. Those are not arbitrary locations, but are there because of the progression of the members of the population from one location to the other during processing. At any point in time, some members will be at each location. Once the locations are given their proper weight, (and even if they are not) it is clear that Applicant and Petrick are not claiming the same invention, so that Applicant can successfully swear behind Petrick. Moreover, the Berney reference teaches only the use of a tag within a laboratory, and not among the various facilities of Applicant's invention. All of the rejections should be withdrawn and the claims allowed.

Respectfully submitted,

Howard A. MacCord, Jr.
Registration No. 28,639
MacCord Mason PLLC
P. O. Box 2974
Greensboro, NC 27402
(336) 273-4422

Date: June 9, 2010
File No.: 2552-011

[45] Paragraph 17 of Office Action mailed January 10, 2006.